SEP - 2 2011 K110860

Omron Healthcare, Inc.
1200 Lakeside Drive
Bannockburn,IL 60015 USA

Tel - 847-247-5626
Fax - 847-247-5626

Official Contact: Mirna DiPano – Director, Quality & Regulatory

Proprietary or Trade Name: NE-C801 Nebulizer Compressor system

Common/Usual Name: Nebulizer (direct patient interface)

Classification Name/Code: CAF
Nebulizer (direct patient interface)
CFR 868.5630

Device: NE-C801 nebulizer compressor system

Modified Device: Omron – NE-C28 – K060811

Device Description:
The Omron NE-C801 nebulizer compressor system is a standard nebulizer compressor system with an integral compressor and handheld, pneumatic nebulizer intended for general purpose use. It is powered by standard AC. This is a modification of the NE-C28 cleared under K060811.

The modifications to the device do not change the intended use of the predicate device. The modifications to the device do not alter the fundamental scientific technology. As there are no changes in hardware that will impact performance, there is no need to validate the changes through a clinical investigation.

Indications for Use:
The NE-C801 Nebulizer Compressor System is intended to provide air to the pneumatic nebulizer in order to aerosolize medications for inhalation by the patient for respiratory disorders. The system is designed for use with pediatric (defined by the prescribed medication) and adult patients in the home, hospital, and sub-acute settings.

Patient Population:
Pediatric (defined by the prescribed medication) and adult patients

Environment of Use:
Home, hospital, and sub-acute settings

Contraindications:
None

Summary of Modifications:

The modifications to the device do not change the intended use of thepredicate device. The modifications to the device do not alter the fundamental scientific technology. As there are no changes in hardware that will impact performance, there is no need to validate the changes through a clinical investigation.

Modifications:

- Minor changes to nebulizer design
- Changes to physical dimensions
- Change to compressor design to make it smaller and lighter weight

There is no change in intended use, including patient population and environment of use. There is no change in contraindications.

Performance Testing:

Verification activities, as required by the risk analysis, for the modification were performedby the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met. **Table 1** summarizes the comparison and **Table 2** the testing.

Table 1 – Comparison and Equivalence of Model NE-C801 and the Predicate

Features	New NE-C801	Predicate (K060811) NE-C28
Indications for use	The NE-C801 Nebulizer Compressor System is intended to provide air to the pneumatic nebulizer in order to aerosolize medications for inhalation by the patient for respiratory disorders.	The Omron Compressor Nebulizer Systems include a compressor and nebulizer, Model NE-C28 uses an AC powered compressor. The electrically powered compressor provides compressed air to the supplied pneumatic nebulizer to aerosolize drugs for inhalation by the patient. The nebulizer which when driven by the integral air compressor, nebulizes specific inhalable drugs for inhalation by a patient for treatment of respiratory disorders such as allergies, asthma, cystic fibrous, COPD, etc.
Environment of Use	Home, Hospital, Sub-acute settings	Same
Patient Population	Pediatric (defined by the prescribed medication) and adult patients	Same – Pediatric and adult
Contraindications	None	None
Principle of Operation	Pneumatic (gas powered) jet nebulizer	Pneumatic (gas powered) jet nebulizer
Aerosolization	Continuous during inhalation and exhalation	Continuous during inhalation and exhalation
Compressed gas source	Nebulizer compressor Wall air / oxygen with flow rate control	Nebulizer compressor Wall air / oxygen with flow rate control
Typical flow rate	8 lpm	8 lpm

Features	New NE-C801	Predicate (K060811) NE-C28
Components available in kit with nebulizer	Mouthpiece / Hose Face Mask Oxygen / Delivery tubing Aerosol tee	Mouthpiece / Hose Face Mask Oxygen / Delivery tubing Aerosol tee
Component / Accessories intended use	All are single patient, multi-use	All are single patient, multi-use
Standards met	IEC 60601-1 IEC 60601-1-2	IEC 60601-1 IEC 60601-1-2
Operating conditions	10°C to 40°C 30% to 85% RH	10°C to 40°C 30% to 85% RH
Storage conditions	-20°C to 60°C 10% to 95% RH	-20°C to 60°C 10% to 90% RH
Dimensions (mm)	142(W) x 72(D) x 98(H)	165(W) x 260(D) x 121(H)
Weight (kg)	0.270 kg	2.5 kg

Performance		
Materials ISO 10993	Identical to K060811	
Particle Characterization per Cascade Impactor		
Total Delivered Dose (ug) Mean	Pulmicort – 391.1 Intal – 12368.9 Salbutamol – 7883.3	Pulmicort – 401.6 Intal – 12233.3 Salbutamol – 7972.2
Total delivered Dose fraction (%)	Pulmicort – 78.2% Intal – 61.8% Salbutamol – 77.0%	Pulmicort – 80.3% Intal – 61.2% Salbutamol – 79.7%
Particle size (MMAD) (Microns)	Pulmicort – 3.88 Intal – 2.91 Salbutamol – 2.54	Pulmicort – 3.73 Intal – 2.71 Salbutamol – 2.35
Geometric Std. Dev. (GSD)	Pulmicort – 1.93 Intal – 2.27 Salbutamol – 2.62	Pulmicort – 2.05 Intal – 2.29 Salbutamol – 2.59
Respirable Fraction (% Mass 0.5-5 microns)	Pulmicort – 61.9% Intal – 70.5% Salbutamol – 66.4%	Pulmicort – 62.7% Intal – 72.8% Salbutamol – 69.2%
Total Respirable Dose (ug 0.5 -5.0 microns)	Pulmicort – 242.2 Intal – 8729.5 Salbutamol – 5335.0	Pulmicort – 251.9 Intal – 8894.8 Salbutamol – 5514.4
Medication captured on USP Throat (ug)	Pulmicort – 13.3 Intal – 253.6 Salbutamol – 144.9	Pulmicort – 14.9 Intal – 213.4 Salbutamol – 141.4
Medication captured on USP Throat Fraction (%)	Pulmicort – 3.4% Intal – 2.0% Salbutamol – 1.8%	Pulmicort – 3.8% Intal – 1.7% Salbutamol – 1.8%
Medication retained in Device (ug)	Pulmicort – 96.1 Intal – 8000.0 Salbutamol – 2072.2	Pulmicort – 104.4 Intal – 7533.3 Salbutamol – 1977.8
Medication Retained in Device Fraction (%)	Pulmicort – 19.2% Intal – 40.0% Salbutamol – 41.4%	Pulmicort – 20.9% Intal – 37.7% Salbutamol – 39.6%

Features	New NE-C801	Predicate (K060811) NE-C28
Particle Characterization per Cascade Impactor		
Coarse Particle (>4.7 um) Fraction (%)	Pulmicort – 37.1% Intal – 27.7% Salbutamol – 26.6%	Pulmicort – 35.3% Intal – 25.0% Salbutamol – 24.6%
Fine Particle (<4.7 um) Fraction (%)	Pulmicort – 59.6% Intal – 70.2% Salbutamol – 71.6%	Pulmicort – 60.9% Intal – 73.2% Salbutamol – 73.7%
Ultra Fine Particle (um) Fraction (%)	Pulmicort – 3.5% Intal – 8.9% Salbutamol – 16.9%	Pulmicort – 5.4% Intal – 9.4% Salbutamol – 0.19%
Nebulization rate (g/ml)	Pulmicort – 0.37 Intal – 0.30 Salbutamol – 0.37	Pulmicort – 0.44 Intal – 0.35 Salbutamol – 0.41
Confidence level of testing	The test and number of samples (3) with 3 runs provided a 95% confidence level	The test and number of samples (3) with 3 runs provided a 95% confidence level

Table 2 – Particle Characterization results at 95% confidence

A series of aerosol performance tests were performed using an 8 stage cascade impactor at a sampling flow rate of 15 l/min equipped with a USP <601> induction port throat. Aerosol was sampled directly from the outlet. Three (3) device samples were tested with 3 runs each, for a total of 9 sample points per each drug. Aerosol was sampled directly from the outlet. The following table is a summary of results with intervals given for a 95% confidence level.

Mean / Std. Dev	Pulmicort (250 ug/ml)	Intal (10 mg/ml)	Salbutamol (5 mg/ml)
Total delivered Dose (ug)	391.11 ±16.51	12368.89 ±269.61	7883.33 ±116.96
Total Delivered Dose Fraction (%)	78.2% ±3.3%	61.8% ±3.1%	77.0% ±2.5%
Particle Size (MMAD) um	3.88 ±0.28	2.91 ±0.14	2.54 ±0.28
Geometric Standard Deviation	1.93 ±0.20	2.27 ±0.02	2.62 ±0.03
Respirable Fraction (0.5-5 um)	61.9% ±4.0%	70.5% ±1.3%	66.4% ±1.6%
Total Respirable Dose (ug between 0.5-5 um)	242.17 ±18.90	8729.49 ±497.57	5235.02 ±233.61
Medication Captured on USP Throat	13.34 ±3.40	253.66 ±27.42	144.94 ±16.32
Medication Captured on USP Throat Fraction (%)	3.4% ±0.4%	2.0% ±0.1%	1.8% ±0.1%
Medication Retained in Device	96.11 ±9.61	8000.00 ±438.21	2072.22 ±257.90

Mean / Std. Dev	Pulmicort (250 ug/ml)	Intal (10 mg/ml)	Salbutamol (5 mg/ml)
Medication Retained in Device Fraction (%)	19.2% ±1.9%	40% ±2.2%	41.4% ±5.2%
Mean / Std. Dev	Pulmicort (250 ug/ml)	Intal (10 mg/ml)	Salbutamol (5 mg/ml)
Coarse Particle Fraction (%) (>4.7 um)	37.1% +2.9%	27.7% +1.5%	26.6% +2.3%
Fine Particle Fraction (%)(<4.7 um)	59.6% +3.5%	70.2% +1.5%	71.6% +2.3%
Ultra-Fine Particle Fraction & (<1.0 um)	3.5% +1.7%	8.9% +2.1%	16.9% +5.3%

The differences between the proposed device and the predicates are:

- Size
- Slight modification to nebulizer

It is our view that these are not significant differences that affect the safety or effectiveness of the intended device as compared to the predicate device.

Substantial Equivalence:
The NE-C801 is viewed as substantially equivalent to the predicate device because:

Indications for Use:
The Indications for Use are as a general purpose nebulizer and compressor system which is identical to predicate – K060811

Patient Population:
The patient population is pediatric and adult which is identical to predicate – K060811. The pediatric population was defined based upon the limits of the prescribed medication.

Environment of Use:
The environment of use is – home, hospital and sub-acute care settings which is identical to predicate – K060811

Technology:
The technology of the compressor is identical compressor technology to predicate – K060811

The technology of the pneumatic (jet-style) continuous flow nebulization is identical nebulizer technology to predicate – K060811

Materials:
The materials in the gas and fluid pathway are identical to predicate – K060811.

Performance Testing:
We have performed a number of performance tests which are identical to those done with the predicate, K060811. These included:

- IEC 60601-1
- IEC 60601-1-2
- Cascade Impactor particle testing with 3 devices for 3 runs with 3 drugs resulting in a 95% confidence interval
- Compressor testing
    - VOC testing per EPA TO-15
    - $PM_{2.5}$ testing per NIOSH NMAM 0600
    - Ozone testing per OSHA method ID 214

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Omron Healthcare, Incorporated
C/O Mr. Paul Dryden
President
ProMedic, Incorporated
24301 Woodsage Drive
Bonita Springs, Florida 34134

SEP - 2 2011

Re: K110860
Trade/Device Name: NE-C801 Nebulizer Compressor System
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer
Regulatory Class: II
Product Code: CAF
Dated: July 12, 2011
Received: July 13, 2011

Dear Mr. Dryden:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K110860

Device Name: NE-C801 nebulizer compressor system

Indications for Use:

The NE-C801 Nebulizer Ciompressor System is intended to provide air to the pneumatic nebulizer in order to aerosolize medications for inhalation by the patient for respiratory disorders. The system is designed for use with pediatric (defined by the prescribed medication) and adult patients in the home, hospital, and sub-acute settings.

Prescription Use XX (Part 21 CFR 801 Subpart D) **or** **Over-the-counter use _** (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K110860